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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/536,992 | 06/16/2005 | Peter Jeffrey | 05067 | 1002 |
| 23338 | 7590 | 12/05/2006 | EXAMINER | |
| DENNISON, SCHULTZ & MACDONALD 1727 KING STREET SUITE 105 ALEXANDRIA, VA 22314 | | | MEHTA, BHISMA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3767 | |

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/536,992 | JEFFREY, PETER | |
| | Examiner Bhisma Mehta | Art Unit 3767 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 31 May 2005.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 22-42 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 22-32 and 34-42 is/are rejected.
 7) Claim(s) 33 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 31 May 2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>6/16/2005</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the means for release of the coupling must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the

description: 101, 115, 533B, 533S, and 831T. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 101S, 118H, 112S, and 850B. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The disclosure is objected to because of the following informalities: In line 27 of page 10, the reference to Figure 2 is unclear because there is no drawing labeled Figure 2. Appropriate correction is required.

Claim Objections

5. Claims 23, 24, 31-33, 37, 38, 41, and 42 are objected to because of the following informalities: Claims 23, 24, 41, and 42 recite the limitation "said drive coupling" in line 3. Claim 31 recites the limitation "the co-operating driving part" in line 2. Claim 32 recites the limitation "the co-operating driving part" in line 1. Claim 33 recites the limitation "the co-operating driving part" in line 1 and "the driving and driven parts" in lines 4-5. Claim 37 recites the limitations "the additional force transmitting means" in lines 1-2 and "the driving parts" in lines 2-3. Claim 38 recites the limitations "the additional force transmitting means" in lines 1-2 and "the co-operating driving parts" in lines 2-3. There is insufficient antecedent basis for these limitations in these claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 22-25 and 40-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention. In claims 22 and 40, it is unclear if the triggering means which release the coupling are being claimed in addition to the means for release of the coupling or if the triggering means and the means for release of the coupling are drawn to the same structure.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 22, 24-32, 34-40, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Kirchhofer et al (U.S. Patent No. 6,280,421).

Kirchhofer et al teach a hollow needle applicator having an applicator body (2,3), a piston assembly, and a force applying actuator (10) with at least one force transmitting part (12) which provides a coupling to the piston assembly. In Figure 2a, the applicator is shown with a provision for automatic needle retraction in the form of spring means (51) which is arranged within a forward portion of the applicator. The applicator also has means for release of the coupling (21). The piston assembly comprises a deformable piston (K), a hollow piston rod (20), and a triggering means (22). As to claim 24, the piston rod (20) has driven extension parts (shown at 18 in Figure 1a) which co-operate with the force transmitting part (12) and are deflectable towards each

other and the triggering means is in the form of a collar. As to claim 25, Kirchhofer et al teach a drive coupling ring (40).

As to claim 26, In figure 3a, Kirchhofer et al show a hollow needle applicator having an applicator body (2,3), and a force applying actuator (10) mounted in the body to drive a carrier where the actuator and carrier have co-operating drive (7) and driven (shown at the part of 3 which contacts 7) parts. The applicator also includes release formation means (shown proximal of 3). As to claims 27-29, the release formation means comprises at least one deflector element which is integrally formed with the applicator body and projects rearwardly. As to claim 30, the co-operating drive part (7) of the actuator comprises at least one deflectable extension of the actuator. As to claims 31 and 32, the release formation means is arranged to deflect the co-operating drive part of the actuator outwardly of the co-operating driven part and these parts are in direct contact with each other prior to their release. As to claim 34, the actuator is driven by a drive spring (5) which includes a release mechanism (6). As to claim 35, the movement of the cartridge is limited by a shoulder (31) against an internal ledge or projection of the applicator body. As to claim 36, the applicator includes a piston assembly and the actuator has at least one additional force transmitting part (12). As to claims 37 and 38, the additional force transmitting part or means is axially parallel to the drive part of the actuator and arranged radially inside the co-operating drive part of the actuator. As to claim 39, in Figure 2a, the applicator is shown with a provision for automatic needle retraction in the form of spring means (51) which is arranged within a forward portion of the applicator and includes means for release of the coupling (21).

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As to claim 40, the piston assembly has a deformable piston (K), a hollow piston rod (20), and a triggering means (22). As to claim 42, the piston rod (20) has driven extension parts (shown at 18 in Figure 1a) which co-operate with the additional force transmitting part (12) and are deflectable towards each other and the triggering means is in the form of a collar.

Allowable Subject Matter

10. Claims 23 and 41 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

11. Claim 33 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wyrick (U.S. Patent No. 5,695,472) and Buttgen et al (U.S. Patent No. 6,015,396) disclose hollow needle applicators.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-

3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



BM

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

